REMARKS

Responsive to the Requirement for Restriction made by the Examiner, the Applicants hereby cancel claims 1 and 2 without prejudice. In addition, claim 3 has been amended to delete the phrase "or a gene encoding the same." Thus, claims 3 and 4, directed to the elected invention, remain in the application.

Accordingly, the objection to claims 3 and 4 has been rendered moot.

Claims 3 and 4 have been rejected under 35 USC 102(e) as being anticipated by U.S. Patent No. 6,732,738 (Komeda et al.). Claims 3 and 4 have also been rejected under 35 USC 103(a) as being unpatentable over WO 00/13710 (Jennings et al.) in view of Ikada et al. (USP 6,831,058).

These rejections are respectfully traversed. Reconsideration and withdrawal thereof are requested.

On page 4, lines 4-7 of the Office Action, the Examiner states that "While Komeda et al. do not specifically state 'coronary artery narrowing or blockage,' this would be inherent to the patient population which is being treated by Komeda et al." The Applicants respectfully disagree. The term "coronary artery disease" is a generic term and has a broader concept which generally covers any diseases observed in the coronary artery. It includes not only "coronary artery narrowing or blockage," but also many other diseases of the coronary artery which could be caused by different mechanisms. On the other hand, the disease to be treated by the present invention, i.e., "coronary artery narrowing or blockage" is more specific and has a narrower concept. Even if a drug is found to be effective in treating a certain type of coronary artery disease, one cannot expect that the drug is also effective in treating "coronary artery narrowing or blockage." Thus, the phrase "coronary artery narrowing or blockage" is not inherent to and thus not anticipated from the general term "coronary artery disease."

As far as anticipation is concerned, a claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference; *Verdegaal Bros. v. Union Oil Co. of California*, 2 USPQ2d 1051 (Fed. Cir. 1987). U.S. case law also states that "The identical invention must be shown in as complete detail as is contained in the ... claim"; *Richardson v. Suzuki Motor Co.*, 9 USPQ2d 1913 (Fed. Cir. 1989). See also MPEP Sect. No. 2131.

Further, the Federal Circuit has stated that "there is no anticipation 'unless all of the same elements are found in exactly the same situation and united in the same way ... in a single prior art reference."; *Perkin-Elmer Corporation v. Computervision Corporation*, 221 USPQ 669 (Fed. Cir. 1984), citing *Kalman v. Kimberly-Clark Corp.*, 218 USPQ 781 (Fed. Cir. 1983).

Since there is no specific disclosure or teaching of treating "coronary artery narrowing or blockage" in the Komeda reference, the basis for anticipation fails and the rejection under 35 USC 102(e) must be withdrawn.

With regard to the Jennings et al. '710 publication and the Ikada et al. "058 patent, it appears that the Examiner has overlooked a main feature of the present invention wherein the gelatin hydrogel is crosslinked before being complexed with the angiogenesis factor.

As the Applicants stated in the previous argument, the present invention is characterized in that the hydrogel is obtained by chemical crosslinking of gelatin, which allows for the control of *in vivo* degradation of the hydrogel and, thus, enables sustained release of angiogenesis factors for a long time. As disclosed in the specification, the hydrogel of the present invention allows for sustained release of a growth factor for two weeks. In contrast, the hydrogel of Jennings et al. is not crosslinked, and can provide a slow-release of drugs for only several hours, as shown in the data of Figs. 5 and 6, which is not long enough to treat cardiac diseases.

Moreover, according to the present invention, the angiogenesis factors retain their biological activity because they are not chemically linked to the hydrogel. The angiogenesis factors are attached to the hydrogel via physical (mainly electrostatic) interaction, and thus are slowly released in accordance with the degradation of the hydrogel, not through a simple diffusion. As a consequence, the angiogenesis factors having biological activity will be released in a desired release pattern and hence can exert activity at a local area for a long period of time, which leads to improved therapeutic results.

The working examples of the present invention show a remarkable therapeutic effect of the sustained release preparation of the present invention, which could not have been expected by those skilled in the art, absent hindsight taken from the Applicants' own disclosure.

Thus, it is submitted that the Examiner has not presented a *prima facie* case of obviousness and that the present claims define a novel and non-obvious invention.

Simply stated, the Jennings '710 publication does not specifically disclose or teach the treatment of coronary artery narrowing or blockage. Since "coronary artery disease" is not the same as and not predictive of treatment of coronary artery narrowing or blockage, it is believed that the Applicants are justified in asserting that claims 3 and 4 represent allowable subject matter.

In view of the above amendments and remarks, reconsideration of the rejections and favorable action on all of the claims are earnestly solicited.

Should there be any outstanding matters that need to be resolved in the present application, the Examiner is respectfully requested to contact Raymond C. Stewart Reg. No. 21,066 at the telephone number of the undersigned below, to conduct an interview in an effort to expedite prosecution in connection with the present application.

If necessary, the Commissioner is hereby authorized in this, concurrent, and future replies to charge payment or credit any overpayment to Deposit Account No. 02-2448 for any additional fees required under 37.C.F.R. §§1.16 or 1.147; particularly, extension of time fees.

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Respectfully submitted,

By _____

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